

10/523892

DT05 Rec'd PCT/PTO 04 FEB 2005
3433-473

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PCT application of) Authorized Officer:
COOK BIOTECH INCORPORATED) Brian Pellegrino
)
International Application)
Number PCT/US03/27695) Mailing Date
) 14 September 2004
International Filing Date)
04 September 2003) Agent's File
) Reference:
Title of Invention) 3433473COOKB
TISSUE GRAFT PROSTHESIS)
DEVICES CONTAINING JUVENILE OR)
SMALL DIAMETER SUBMUCOSA)

RESPONSE TO WRITTEN OPINION

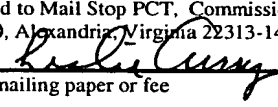
Mail Stop PCT
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Attn: IPEA/US

Dear Sir/Madam:

"Express Mail" label number EVS27598820WS
Date of Deposit September 14, 2004

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Signature of person mailing paper or fee

In response to the Written Opinion mailed 16 July 2004, the Applicant Cook Biotech Incorporated makes the following remarks.

The positive indications with regard to the Novelty of claims 16 and 24 and the Industrial Applicability of claims 1-40 are hereby acknowledged with appreciation. The Applicant requests reconsideration of the negative indications with regard to the Novelty of claims 1-15, 17-23 and 25-40, and with regard to the Inventive Step of claims 1-40, for the following reasons.

The Written Opinion asserts that claims 29, 30, 33, 34, and 37 lack novelty under PCT Article 33(2) as being anticipated by Kropp et al. The Written Opinion notes that Kropp discloses using SIS obtained from a pig. Without explanation or basis, the Written Opinion then states "the Examiner is interpreting the use of the term 'pig' to mean juvenile." This is an improper use of the Kropp reference, which contains no teaching whatsoever as to using juvenile submucosa, as expressly required by the present claims. As is well established in jurisdictions around the world, in order to defeat the

novelty of a claim, a reference must without question teach each and every aspect of the claim. The Kropp reference has no more than a general statement of the use of small intestinal submucosa. There is no teaching of the use of small intestinal submucosa from a juvenile animal. Accordingly, in no way does Kropp negate the novelty of claims 29, 30, 33, 34 and 37. This objection should be withdrawn.

The Written Opinion asserts that claims 1-15, 17-23, and 25-40 lack novelty under PCT Article 33(2) as being anticipated by Termin et al. This rejection is also without proper support and should be withdrawn. In a similar fashion to the first objection discussed above, the Written Opinion simply states that "the Examiner is interpreting the use of the term 'pig' to be mean juvenile." As discussed above, in order to defeat novelty, a reference must teach and every aspect of the claim. In the present case, nowhere does Termin teach or suggest the use of submucosa from a juvenile pig or other animal. Still further, the Written Opinion states that "Termin also discloses the prosthesis can be up to 12 mm. It is inherent that an intact tubular submucosa has an internal diameter no greater than 12 mm since it used to make a graft having a diameter up to 12 mm."

It appears from this discussion that the Examiner is assuming that Termin teaches the use of intact submucosa tubes to make the Termin grafts. This is a false assumption. The Termin patent, in column 6, lines 45+, discloses various ways that the submucosa material can be "tubulated". Each of these involves taking a submucosa material, forming it into a tube, and creating a seam in one fashion or another. Further to the point, such a process in which the ultimate prosthesis lacks an intact submucosa tube is described in Example 1 appearing in column 9 of the Termin patent.

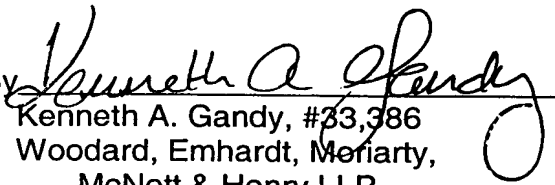
In view of these facts, the objection to claims 1-15, 17-23, and 25-40 is improper and should be withdrawn.

The Written Opinion asserts that claims 16 and 24 lack inventive step under PCT Article 33(3) as being obvious over Termin et al. in view of Cook et al. This objection is traversed essentially for the reasons discussed above. While Termin et al. and Cook et al. generally discuss the use of submucosa material, neither teaches the use of juvenile submucosa material. Both claims 16 and 14 are ultimately dependent upon claim 1, which requires juvenile submucosa. As such, claims 16 and 24 clearly possess inventive

step over the combination of Termin et al. and Cook et al. This objection thus should also be withdrawn.

In view of the foregoing, reconsideration of the claims and the establishment of an International Preliminary Examination Report which is positive is warranted. Prompt such action is requested.

Respectfully submitted

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PATENT COOPERATION TREATY

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JUL 20 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

WRITTEN OPINION

(PCT Rule 66)



Date of Mailing
(day/month/year) **16 JUL 2004**

Applicant's or agent's file reference

3433473COOKB

REPLY DUE

within 2 months/days from
the above date of mailing

International application No.

PCT/US03/27695

International filing date (day/month/year)

04 September 2003 (04.09.2003)

Priority date (day/month/year)

06 September 2002 (06.09.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 2/06 and US Cl.: 623/1.1

Applicant

COOK BIOTECH INCORPORATED

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 06 January 2005 (06.01.2005)

Name and mailing address of the IPEA/US

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Authorized officer

Brian Pellegrino

Telephone No. 703-308-0858

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-23, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages 24-29, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1-4, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International Application No.
PCT/US03/27695

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>16,24</u>	YES
	Claims <u>1-15,17-23,25-40</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-40</u>	NO
Industrial Applicability (IA)	Claims <u>1-40</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 29,30,33,34,37 lack novelty under PCT Article 33(2) as being anticipated by Kropp et al. Kropp et al. disclose a method of using porcine small intestine submucosa for urinary tract repair. Kropp also discloses the SIS is obtained from a pig. The examiner is interpreting the use of the term "pig" to mean juvenile.

Claims 1-15,17-23,25-40 lack novelty under PCT Article 33(2) as being anticipated by Termin et al. Termin discloses the use of porcine submucosa for tissue grafts. Figs. 1A-1C show that multiple layered grafts can be constructed. Termin also discloses that synthetic polymers can be used for the additional layers and that collagen gel layers can also be applied to the tubular graft. The collagen can be obtained from a natural source, such as bovine species. Termin additionally discloses a method of treating a patient with a collagen prosthesis. Termin discloses the small intestine graft is taken from a pig. The examiner is interpreting the use of the term "pig" to mean juvenile. Termin also discloses the prosthesis can be up to 12mm. It is inherent that an intact tubular submucosa has an internal diameter no greater than 12mm since it used to make a graft having a diameter up to 12mm.

Claims 16,24 lack an inventive step under PCT Article 33(3) as being obvious over Termin et al. in view of Cook et al. Termin et al. is explained supra. However, Termin fails to disclose that the SIS is obtained from an adult donor. Cook et al. teach that adult hogs are used for obtaining SIS. It would have been an obvious matter of design choice to use adult SIS as taught by Cook with the graft prosthesis of Termin such that it provides a larger diameter vessel to implant in a patient needing a larger prosthesis.

----- NEW CITATIONS -----

WRITTEN OPINION

International Application No.
PCT/US03/27695

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.